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# Pharmas Face New Pressure To Put Patients Before Profits After GlaxoSmithKline Record $3 Billion Health Care Fraud & FDCA Settlement

***Qui Tam Claims Played Big Role In The Development of Many Charges***

*July 11, 2012*

Pharmaceutical companies will need to carefully study and consider how to react to "groundbreaking" business practice reforms global health care giant GlaxoSmithKline LLC ("GSK") has agreed to implement as part of the record $3 billion criminal and civil agreement resolving federal health care fraud and drug marketing charges following its July 2, 2012 guilty plea in **U.S. v. GlaxoSmithKline PLC Complaint**. Justice Department and Food & Drug Administration (FDA) officials have signaled they expect industry businesses to "follow suit" by adopting business practice reforms that GSK has agreed to implement in the five year Corporate Integrity Agreement it entered into as part of collection of criminal plea agreements and accompanying civil settlements that is resulting in the largest combined federal and state health care fraud recovery in a single global resolution against a pharmaceutical company in the history of the United States. Meeting this expectation will require most pharmaceutical companies to significantly change research and marketing, compensation and other workforce management, board governance and other fundamental business practices well beyond the reforms already being implemented in response to the past decade's enforcement war against the industry.

## Snapshot of U.S. v. GlaxoSmithKline PLC Civil & Criminal Charges & Settlement

After GSK plead guilty on July 2, 2012 to criminal charges it illegally marketed three drugs, the Federal Court in Massachusetts on July 5, 2012 approved a Justice Department sentencing recommendation that incorporated the settlement agreement. In recommending approval of the settlement agreement, the Justice Department told the Court GSK's commitment to 'put patients before profits' by make sweeping reforms to its marketing and other business practices justified approving the settlement agreement in lieu of imposition of probation or other sanctions.

To resolve the criminal charges, GSK agreed to pay a criminal fine of $956,814,400, and criminal forfeiture in the amount of $43,185,600, for a total amount of $1 billion. Along with its criminal guilty plea, GSK also agreed to pay amount additional $2 billion to the U.S as restitution to the federal health care programs and other civil payments and implement an unprecedented list of business practice changes that will revolutionize its sales, marketing and drug efficacy study practices. For more details, see **Justice Department GSK Settlement Fact Sheet** and **U.S. v. GlaxoSmithKline PLC Complaint**.

**GSK Misdemeanor Guilty Plea**

On July 2, 2012, GSK plead guilty to three misdemeanor violations of the Food, Drug and Cosmetic Act (FDCA):

- Regarding Paxil, GSK plead guilty to distribution of a misbranded drug due to false and misleading labeling, in violation of 21 U.S.C. §§ 331(a), 333(a)(1) & 352(a);
- Regarding Wellbutrin, GSK plead guilty to distribution of a misbranded drug due to inadequate directions for use, in violation of 21 U.S.C. §§ 331(a), 333(a)(1) & 352(f)(1); and
- Regarding Avandia, GSK will plead guilty to failure to report data to the FDA, in violation of 21 U.S.C. §§ 331(e), 333(a)(1) & 355(k)(1).

The misdemeanor guilty pleas resolved Justice Department charges GSK engaged is a series of serious violations of federal law in the marketing of Paxil, Wellbutrin and Avandia.

- *Paxil*

The Justice Department charged that from April 1998 to August 2003, GSK unlawfully promoted Paxil for treating depression in patients under age 18, even though the FDA has never approved it for pediatric use. The United States alleges that, among other things, GSK participated in preparing, publishing and distributing a misleading medical journal article that misreported that a clinical trial of Paxil demonstrated efficacy in the treatment of depression in patients under age 18, when the study failed to demonstrate efficacy. At the same time, the United States alleges GSK did not make available data from two other studies in which Paxil also failed to demonstrate efficacy in treating depression in patients under 18. The Justice Department also charged that GSK sponsored dinner programs, lunch programs, spa programs and similar activities to promote the use of Paxil in children and adolescents. GSK paid a speaker to talk to an audience of doctors and paid for the meal or spa treatment for the doctors who attended. Since 2004, Paxil, like other antidepressants, included on its label a "black box warning" stating that antidepressants may increase the risk of suicidal thinking and behavior in short-term studies in patients under age 18. GSK pled guilty to misbranding Paxil in that its labeling was false and misleading regarding the use of Paxil for patients under 18, and was sentenced to pay a criminal fine in the amount of $159,768,000 for its unlawful conduct concerning Paxil.

- *Wellbutrin*

The Justice Department charged that from January 1999 to December 2003, GSK promoted Wellbutrin, approved at that time only for Major Depressive Disorder, for weight loss, the treatment of sexual dysfunction, substance addictions and Attention Deficit Hyperactivity Disorder, among other off-label uses. The United States contends that GSK paid millions of dollars to doctors to speak at and attend meetings, sometimes at lavish resorts, at which the off-label uses of Wellbutrin were routinely promoted and also used sales representatives, sham advisory boards, and supposedly independent Continuing Medical Education (CME) programs to promote Wellbutrin for these unapproved uses. GSK pled guilty to misbranding Wellbutrin in that its labeling did not bear adequate directions for these off-label uses, and was sentenced to pay a criminal fine in the amount of $554,433,600 for its unlawful conduct concerning Wellbutrin.

- *Avandia*

The Justice Department charged that between 2001 and 2007, GSK failed to include certain safety data about Avandia, a diabetes drug, in its Annual Reports to the FDA meant to allow the

FDA to determine if a drug continues to be safe for its approved indications and to spot drug safety trends. The missing information included data regarding certain post-marketing studies, as well as data regarding two studies undertaken in response to European regulators' concerns about the cardiovascular safety of Avandia. Although GSK provided the data to the FDA in other forms, it was not provided as required in the Annual Reports. Since 2007, the FDA has added two black box warnings to the Avandia label to alert physicians about the potential increased risk of (1) congestive heart failure, and (2) myocardial infarction (heart attack). GSK pled guilty to failing to report data to the FDA and was sentenced to pay a criminal fine in the amount of $242,612,800 for its unlawful conduct concerning Avandia.

Given the ongoing aggressive investigation and enforcement of federal drug and health care fraud laws by the Justice Department and Food and Drug Administration and the Justice Department's stated hope that the rest of the pharmaceutical industry will adopt similar reforms to those GSK has committed to implement in connection with its sentence, pharmaceutical companies will want to carefully examine the "groundbreaking" marketing and other business practice reforms that GSK has committed to implement for insights about what federal prosecutors and regulators expectation expect companies involved in the industry to do to reform their marketing, research and other practices.

In encouraging the Court to approve a total of $1 billion of criminal penalties as the sanction for the criminal charges, Justice Department officials argued GSK's commitment under the related civil resolution agreement to make "groundbreaking" business practice reforms to ensure better behavior by its sales force, and to ensure full, fair and accurate reporting of scientific data from GSK studies justified the penalty in lieu of probation or other sanctions.

**GSK $2 Billion Civil Settlement Payments**

The criminal sentence approved by the Court is part of a broader series of criminal, civil and administrative agreements reached between GSK and federal officials. The civil and administrative agreements included in the package deal include three civil settlements that resolve health care fraud and qui tam claims arising from GSK's marketing, sales and health program billings relating to various drugs.

Under the civil settlement agreement, GSK will make sweeping business practice reforms specified in a corporate integrity agreement as well as pay $2 billion in civil damages to federal and state health care programs, which is the largest civil recovery from a drug company in a single global resolution.

The settlement package actually includes three civil settlement agreements.

One civil settlement resolves allegations relating to false claims to federal health care programs resulting from marketing and promotion practices, including off-label marketing. The United States alleges that:

- GSK promoted Paxil, Wellbutrin, Advair, Lamictal and Zofran for uses that were not approved as safe and effective by the Food and Drug Administration; and
- GSK paid kickbacks to doctors to induce them to prescribe Advair, Flovent, Imitrex, Lotronex, Paxil, Wellbutrin, and Valtrex and other drugs, critically undermining the doctors' independent clinical judgment.

A second civil settlement resolves allegations that GSK promoted Avandia to physicians and other health care providers with false and misleading representations, causing false claims to be submitted to federal health care programs. The United States alleges that:

- GSK misleadingly represented that Avandia had a positive lipid, or cholesterol, profile despite having no well-controlled studies sufficient to support that message and despite information on the FDA-approved label stating that Avandia was associated with statistically significant increases in LDL and HDL cholesterol; and
- GSK sponsored programs which suggested cardiovascular benefits from Avandia therapy, despite warnings on the FDA-approved label regarding congestive heart failure and other cardiovascular issues.

A third settlement resolves allegations that GSK reported false best prices to the Department of Health and Human Services and as a result underpaid quarterly rebates owed under the Medicaid Drug Rebate Program. Under federal law, pharmaceutical companies are required to give Medicaid the best price on medications that they offer to any customer. The Justice Department contends that GSK improperly "bundled sales" arrangements that included steep discounts known as "nominal prices" and yet failed to take such contingent arrangements into account when calculating and reporting its best prices to HHS.

**Qui Tam Claims Played Big Role In Development Of Many Charges**

The settlement emphasize both the strong commitment by the Department of Justice and HHS to find a prosecute Medicare and Medicaid financial fraud and the growing importance of qui tam actions and other insider reports of legal violations to the success of these actions.

Qui tam and other fraud reports made by employees or other business partners have become a significant tool in the Federal government's war against health care fraud. Under the False Claims Act, private citizens acting as relators can bring suit on behalf of the United States and share in the recovery. Furthered in part by a series of qui tam claims, whistleblower suits clearly played a role in many of the GSK charges.

The off-label civil settlement also resolves allegations set forth in the following lawsuits filed against GSK under the qui tam, or whistleblower, provisions of the federal False Claims Act, 31 U.S.C. § 3730:

- *U.S. ex rel. Thorpe et al. v. Smith Kline Beecham Inc. and GlaxoSmithKline PLC d/b/a GlaxoSmithKline*, Civil Action No. 11-10398 (D. Mass, transferred from D. Colo.) (filed 1/1/03);
- *U.S. ex rel. Gerahty et al. v. GlaxoSmithKline PLC and SmithKline Beecham Corp. d/b/a GlaxoSmithKline*, (D. Mass.), Civil Action Number 03-10641 (D. Mass.) (filed 4/7/03);
- *U.S. ex rel. Graydon v. GlaxoSmithKline PLC*, Civil Action No. 11-10741 (D. Mass.) (filed 6/5/09);
- *U.S. ex rel. LaFauci v. GlaxoSmithKline PLC*, Civil Action No. 11-10921 (D. Mass.) (filed 8/7/09).

There were no whistleblowers in the Avandia or pricing investigations.

Under the settlement package negotiated to resolve these civil claims, GSK has agreed to pay $2 billion in civil damages. The $2 billion of civil damages include:

- $1,043,000,000 in civil damages to resolve allegations relating to false claims arising from the off-label promotion and kickback allegations relating to Paxil, Wellbutrin, Advair, Lamictal, Zofran, Flovent, Imitrex, Lotronex and Valtrex;
- $657,000,000 in civil damages to resolve allegations relating to misrepresentations about Avandia;
- $300,000,000 in civil damages to resolve allegations relating to false reporting of best prices.

Justice Department officials say the $2 billion civil settlement is allocated as follows:
Federal Recovery:

- Federal recovery of $1,501,618,568 to be distributed among the following programs: Medicare, Medicaid, Department of Defense (TRICARE), Office of Personnel Management (Federal Employee Health Benefits Plan), Department of Veterans Affairs, U.S. Postal Service and Department of Labor (Office of Workers' Compensation Programs); and
- State and Public Health Service (PHS) recovery of $498,381,432.

**Corporate Integrity Agreement Requires GSK To "Put Patients Before Profits" Thru "Groundbreaking" Business Practice Reforms**

Pharmaceutical industry businesses should view with grave concern the statements made by Carmen Ortiz, U.S. Attorney for the District of Massachusetts in announcing agreement that with Federal officials "hope the rest of the pharmaceutical industry follows suit" in "putting patients before profits" by adopting the "groundbreaking" business practice reforms set forth in the a five-year Corporate Integrity Agreement with the Office of Inspector General of the Department of Health and Human Services.

The Justice Department officials announcing the settlement enhanced accountability, increased transparency and wide- ranging monitoring activities conducted by both internal and independent external reviewers. Specifically, among other things, the agreement requires:

- Abolishment of incentive sales compensation; instead, the sales force will be compensated based on business acumen, customer engagement, and scientific knowledge of GSK products;
- Clawback of up to 3 years of annual performance pay (annual bonus and long term incentives) for executives discovered to be involved in significant misconduct;
- Publication of all GSK human research studies, not just those with positive outcomes for GSK drugs;
- Publication of final clinical trial protocols to allow outside researchers to meaningfully analyze the results of GSK studies;
- Removal of commercial influence on the determination of which GSK studies will be conducted; instead, studies will be conducted on scientific merit;
- Removal of commercial influence on the determination of which GSK studies will be published and when; instead, studies will be published when the study is complete, not to create a buzz around a drug;
- Annual certifications by the GSK's Board of Directors that the GSK compliance program is effective, and by GSK's U.S. President that the compliance measures continue and reportable incidents have been properly reported.

**GSK & Other Prosecutions Reflect Need To Tighten Compliance**

Pharmaceutical companies take seriously the need to maintain compliance and tighten marketing and other procedures to promote their ability to defend against the growing risk of federal prosecution signaled by the GSK and other enforcement actions.

In announcing the GSK settlement, Justice Department officials touted the GSK case as demonstrating its "continuing commitment to ensuring that the messages provided by drug manufacturers to physicians and patients are true and accurate and that doctors' decisions as to what drugs are prescribed to sick patients are based on best medical judgments, not false and misleading claims or bad science."

The GSK and other enforcement actions show that Federal officials are acting on this promise. Even before announcing the $3 billion resolution with GSK, the Justice Department and other federal officials accumulated an impressive and growing record of successful investigation and prosecutions. The Justice Department health care fraud union in Boston that lead the GSK prosecution over the past three years already had recovered more than $5.5 billion in settlements, judgments, fines, restitution, and forfeiture in health care fraud cases under the False Claims Act and the Food, Drug and Cosmetic Act before it announced the GSK settlement. Coupled with the overall increase in fraud and FDCA enforcement against pharmaceutical industry providers specifically and health care providers generally nationwide, the GSK decision makes clear that pharmaceutical and other health industry clients need to prepare to withstand ever-tightening expectations and rising enforcement.

In response to the GSK settlement and guilty plea, pharmaceutical companies will need to review their existing and former practices to identify pre-existing and ongoing exposures, and decide what steps to take, if any, to mitigate these risks. In addition to considering what, if any, of the reforms outlined in the GSK Corporate Integrity Agreement to implement and how, these organizations also should consider the workforce management and other internal controls that will help promote compliance with these policies and manage potential whistleblower and other liabilities.

In addition to working to promote compliance with the False Claims Act and other health care laws, pharmaceutical companies and health care providers need to implement strong internal investigation, audit, and employee and contractor management procedures to help self-discover and address potential compliance or other liability concerns. These processes and policies should involve but not be limited to hotlines and other processes for reporting suspected fraud or other misconduct. Most companies also should consider adopting and enforcing strong policies that require employees, contractors and other business partners to timely report and cooperate in the investigation and redress of potential health care fraud or other legal violations, should promptly investigate and redress as needed alleged noncompliance, and should retaliation against individuals making these reports in good faith.

## For More Information Or Assistance

For help reviewing and updating your Stark Law, Anti-Kickback Statute, or other health care compliance, workforce, internal controls and risk management policies, practices or programs; assessing the strength of your organizations existing risk management and compliance controls under these laws or other healthcare laws and regulations; or in addressing other compliance or health care concerns, please contact Cynthia Marcotte Stamer via e-mail **here** or via telephone at 469.767.8872. To review and register to receive other helpful updates or for more information about Ms. Stamer and her experience, see **here**.

Vice President of the North Texas Health Care Compliance Professionals Association, Past Chair of the ABA Health Law Section Managed Care & Insurance Section and the former Board Compliance Chair of the National Kidney Foundation of North Texas, Ms. Stamer has more than 24 years experience advising health industry clients about these and other matters. Her experience includes advising hospitals, nursing home, home health, rehabilitation and other health care providers and health industry clients to establish and administer compliance and risk management policies; prevent, conduct and investigate, and respond to peer review and other quality concerns; and to respond to Board of Medicine, Department of Aging & Disability, Drug Enforcement Agency, OCR Privacy and Civil Rights, HHS, DOD and other health care industry

investigation, enforcement and other compliance, public policy, regulatory, staffing, and other operations and risk management concerns.

A popular lecturer and widely published author on health industry concerns, Ms. Stamer continuously advises health industry clients about compliance and internal controls, workforce and medical staff performance, quality, governance, reimbursement, and other risk management and operational matters. Ms. Stamer also publishes and speaks extensively on health and managed care industry regulatory, staffing and human resources, compensation and benefits, technology, public policy, reimbursement and other operations and risk management concerns. Her insights on these and other related matters appear in the Health Care Compliance Association, Atlantic Information Service, Bureau of National Affairs, The Wall Street Journal, Business Insurance, the Dallas Morning News, Modern Health Care, Managed Healthcare, Health Leaders, and a many other national and local publications. You can get more information about her health industry experience **here**. If you need help responding to concerns about the matters discussed in this publication or other health care concerns, wish to get information about arranging for training or presentations by Ms. Stamer, wish to suggest a topic for a future program or update, or wish to request other information or materials, please contact Ms. Stamer via telephone at (214) 452-8297 or via e-mail **here**.

If you or someone else you know would like to receive future updates about developments on these and other concerns from Ms. Stamer, see **here**.

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- **Ambulance Worker Gets 46 Month Sentence For Defrauding Medicare By Running Company As Disqualified Person**
- **Temple To Pay $1,088,574.93 To Resolve Exposures From Voluntarily Disclosed Improper Health Care Billings**
- **Former Orthofix Executive Pleads Guilty To Anti-Kickback Law Violations**
- **Abbott Labs To Pay $1.5 Billion to Resolve Criminal & Civil Investigations Of Off-Label Promotion Of Depakote**
- **CMS Likely To Tighten Audits & Reimbursement After OIG Says "Extremely High" Retail Pharmacy Billings To Medicare Part D Warrant Close Scrutiny**
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- **Health Care Providers Get Nailed For Using False Statements To Defraud Medicaid, Bankruptcy Court**
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- **Texas Healthcare Operator's Guilty Plea To Bankruptcy Fraud Conspiracy Highlights Broad Prosecution Risks**
- **Arizona Physician Group Pays $100K To Settle HIPAA Charges**
- **Orthofix Medical Device Exec Awaits Sentencing After Pleading Guilty To Violating Anti-Kickback Law**
- **Health Care Providers Also Should Guard Against Rising Exposures To State Health Care Fraud & Other Enforcement Risks**
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- **DOJ & HHS Health Care Fraud Enforcement Nets $4 Billion + In 2011**
- **Broad-Reaching Prosecution Of Individuals Participating In Operations Of Companies Convicted Of Fraud Shows Risks Of Participation**

If you or someone else you know would like to receive future updates about developments on these and other concerns, please be sure that we have your current contact information – including your preferred e-mail – by creating or updating your profile **here**. For important information concerning this communication click **here.**

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